REMARKS

Claims 1-9 and 11-18 are pending in this application. Claims 1 and 2 are amended herein for clarity to more particularly define the invention. Support for these amendments is found in the language of the original claims and throughout the specification, as set forth below. For example, the amendment of claims 1 and 2 to recite 15-26 nucleotides is supported in the specification at least on page 5, line 26. No new matter has been added by these amendments and their entry is respectfully requested. In light of these amendments and the following remarks, applicants respectfully request reconsideration of the application and allowance of the pending claims to issue.

Applicants note that although all of the claims are marked as rejected on the cover page of the Office Action, none of the rejections presented include claim 17. If claim 17 is allowable, applicants respectfully request that a Notice of Allowance be issued so indicating.

I. Withdrawal of finality of the previous Office Action

Applicants acknowledge that the finality of the rejection of the previous Office Action is withdrawn.

II. Rejection under 35 U.S.C. § 112, first paragraph

The Office Action states that claims 1-5, 7-9, 11 and 12 are rejected under 35 U.S. C. § 112, first paragraph, as allegedly failing to comply with the written description requirement on the basis that claims 1 and 2 recite the phrase "consisting essentially of."

Applicants disagree with the Examiner's contention that the claims as presented lack adequate written description. However, in order to expedite

prosecution of this application to issue, claims 1 and 2 are amended to recite "consisting" in place of the phrase "consisting essentially of." Support for this amendment is found throughout the specification, which teaches as various embodiments of this invention a single pair of primers and their use in the methods of this invention. Thus, this rejection has been rendered moot and applicants respectfully request its withdrawal.

III. Rejection under 35 U.S.C. § 102(b)

The Office Action states that claims 1-3 and 8 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent no. 5, 474,796 (Brennan). Specifically, the Office Action states that Brennan discloses preparing oligonucleotides that "represent every possible permutation of the 10-mer oligonucleotide" and that by default, the preparation of every possible 10-mer oligonucleotide would comprise every 10-mer oligonucleotide claimed presently.

Claims 1-3 and 8 are not anticipated by Brennan. Case law very specifically holds and the M.P.E.P. states that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Additionally, anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000). Brennan, at best, discloses nothing more than an alleged METHOD of producing oligonucleotides that purportedly "represent every possible permutation of the 10-mer oligonucleotide," although the patent provides only prophetic examples and no data and discloses a single 10-mer oligonucleotide, which is not even remotely similar to the oligonucleotide pairs of the claimed invention. Claims 1-3 and 8 recite

COMPOSITIONS of specific oligonucleotide primer pairs defined by specific sequences and paired in specific combinations, which are not found in Brennan, either expressly or inherently, as required in order for a reference to anticipate. Thus, the requirements for anticipation under 35 U.S.C. § 102(b) are not met by the disclosure of Brennan and claims 1-3 and 8 are not anticipated by this reference. For these reasons, applicants believe this rejection has been rendered moot and respectfully request its withdrawal and allowance of the pending claims to issue.

IV. Declaration under 37 C.F.R. § 1.131

Applicants note that the Office Action states that the Declaration of February 18, 2004 was sufficient to overcome the Backus et al. (U.S. Patent No. 6,001,558) reference.

V. Rejection under 35 U.S.C. § 103

A. Claims 1-9, 11-14, 16 and 18 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over Montagnier et al. (U.S. Patent No. 5, 221,610) in view of Brennan, Adams et al. (U.S. Patent No. 5, 576, 176) and the Research Genetics Advertisement. Specifically, the Office Action states that Montagnier et al. discloses primers for detecting HIV-1 and of directing primers to conservative regions and that one such region of conserved sequences is found in the LTR.

Although in previous Office Actions, the Examiner acknowledged that Montagnier et al. does not explicitly teach applicants' sequences, it appears that without the availability of the Backus et al. patent as a supporting reference, the Examiner no longer acknowledges this lack of teaching but instead has found new meaning in the teachings of Montagnier et al., which are only now presented although this reference has been the basis of an obviousness rejection a total of seven times in this application. These new revelations include emphasis on the disclosure in Montagnier et al. that the amplification product can range from 10 to 300 nucleotides and of probes to detect the

amplification product. On the basis of this disclosure and no longer able to rely on the Backus et al. patent in support of this rejection, the Examiner contends that the teachings of Montagnier et al. on their own, "...render obvious any primer pair that can be used to amplify HIV LTR sequences, where the amplification product ranges in size from 10 to 300 nucleotides" and that these disclosures are also considered "...to render obvious any probe that would be used to detect any of said amplification products."

The Examiner goes on to combine Montagnier et al. with Brennan in this rejection on the basis that Brennan allegedly teaches developing and using every claimed oligonucleotide that is 10 nucleotides in length, although the Office Action does not mention what use is taught. The Examiner notes that Brennan does not teach developing oligonucleotides of greater length.

The Office Action continues on in this rejection to include Adams et al. as disclosing primers that are used to detect and monitor HIV in patients and as disclosing "Primer 3," which the Examiner alleges encompasses at least 10 nucleotides of each of applicants' primers/probes presented by SEQ ID NOs:1, 2 and 3.

Also included in this rejection is the Research Genetics advertisement that has been cited again and again. Specifically, the Office Action states that the advertisement in Research Genetics discloses for sale a software program that allows the ordinary artisan to set parameters whereby the software will automatically screen all possible sequence comparisons and provide a listing of those primers that meet the established criteria. The Office Action further states that such parameters to be employed in the selection of primer and probe sequences include desired specificity, length, GC content, secondary structure consideration, etc. The Office Action then contends that "...accordingly, the designing of one sequence over that of another, especially when the very source is known and the prior art directs one to use such a sequence, speaks of routine optimization." The Examiner concludes that routine

optimization is not patentable, even if it results in significant improvements over the prior art.

From these alleged disclosures, the Office Action contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the software as described in the Research Genetics advertisement with the teachings of Montagnier et al., Brennan and Adams et al. to select the specifically claimed primers in the specifically claimed combinations and the specifically claimed probes of the present invention.

Applicants respectfully traverse this rejection and maintain their previously asserted position that the claimed invention would not have been obvious to one of ordinary skill in the art at the time this invention was made.

A determination under § 103 that an invention would have been obvious to someone of ordinary skill in the art is a conclusion of law based on fact. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1593, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 107 S.Ct. 2187. After the involved facts are determined, the decision maker must then make the legal determination of whether the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was made. *Id.* at 1596. The United States Patent and Trademark Office ("USPTO") has the initial burden under § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

To establish a *prima facie* case of obviousness, the USPTO must satisfy three requirements. First, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *See In re Wilson* 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art"). Importantly, the teachings must come from the prior art, not from the Appellant's disclosure. *See In re Vaeck*, 947

F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. *In re Oetiker,* 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992); *In re Fine*, 837 F.2d at 1074; *In re Skinner*, 2 U.S.P.Q.2d 1788, 1790 (Bd. Pat. App. & Int. 1986). Third, the proposed modification or combination of the prior art must have a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991).

Under § 103, the cited reference or references must teach or suggest *all* the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. §2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. §2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

As recently emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be ***clear and particular***, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of

references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). In an even more recent decision, the Court of Appeals for the Federal Circuit has stated that, to support combining or modifying references, there must be particular evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

Claim 1 of the present invention provides a pair of oligonucleotide primers, for use as a single primer set in the amplification of a target sequence located within the LTR region of the genome of HIV-1, said primer pair consisting of a first hybridizing oligonucleotide being 10-26 nucleotides in length and comprising at least a fragment of 10 sequential nucleotides of a sequence selected from the group consisting of:
SEQ ID 1: G GGC GCC ACT GCT AGA GA;
SEQ ID 2: G TTC GGG CGC CAC TGC TAG A;
SEQ ID 3: CGG GCG CCA CTG CTA;
and a second hybridizing oligonucleotide being 10-26 nucleotides in length and comprising at least a fragment of 10 sequential nucleotides of a sequence selected from the group consisting of:
SEQ ID 4: CTG CTT AAA GCC TCA ATA AA; and
SEQ ID 5: CTC AAT AAA GCT TGC CTT GA.

Although the Examiner previously acknowledged that Montagnier et al. did not disclose any of applicants' sequences, the Examiner now alleges that the teachings of Montagnier et al. on their own are sufficient to render obvious these specific primer sequences in these specific combinations. However, as applicants have argued again and again, Montagnier et al provides nothing more than a general reference to the use of PCR, that is suggested to be carried out with undefined primer pairs and probes derived from "...highly conserved regions of the viral genome, such as the LTR, qao, and env regions of HIV-1" (Montagnier et al., columns 19 and 20, bridging paragraph). Montagnier et al. does not provide a single example of any primers or

probes and provides no suggestion or motivation to even choose a sequence in the LTR region of the HIV genome over a sequence in the qao or env regions to produce oligonucleotide pairs to detect HIV, much less choose the specific oligonucleotide pairs or their combinations as claimed herein. Thus, it is clear that the specific sequences recited in the claimed invention and in particular, the claimed combinations of sequences would in no way have been obvious to one of ordinary skill in the art from the teachings of Montagnier et al. In fact, as applicants have already pointed out, Montagnier et al. actually teaches away from the present invention by stating that "...the PCR technique using a single primer pair may not produce reliable results." (Column 19, lines 62-63). Montagnier et al. then goes on to state that the preferable technique is to employ several primer pairs. As applicants have pointed out, the present invention is directed to the use of a single primer pair to detect HIV-1 nucleic acid, which would not have been obvious to one of ordinary skill in the art from the teachings of Montagnier et al.

Combining Montagnier et al. with Brennan fails to cure these defects, because as noted above, Brennan discloses nothing more than a purported method of producing every possible 10-mer oligonucleotide, but provides no teaching or suggestion that would motivate one of skill in the art to look to the teachings of Brennan with or without Montagnier et al. to produce the oligonucleotide pairs of claim 1. As noted above, the case law is clear that the motivation to combine references must be ***clear and particular***. It would be readily apparent to anyone of skill in the art that in this combination of references (neither of which provide any supporting data for these disclosures), the broad suggestion that any conserved region of the HIV genome, such as qao, LTR or env, may be a good site for PCR amplification and the broad disclosure of a general method for allegedly producing any possible 10-mer oligonucleotide, provides no clear and particular motivation, as the case law requires, to produce the oligonucleotide pairs of claim 1.

The addition of Adams et al. to the mix still fails to provide the requisite *prima*

facie showing of obviousness. Adams et al. discloses Primer 3, which the Examiner alleges to be encompassing of at least 10 nucleotides of each of applicants' primers/probes as represented by SEQ ID NO:1, SEQ ID NO:2, and SEQ ID NO:3. As an initial point, the oligonucleotides of claim 1 are primers, not probes and are claimed as members of a primer pair, and in particular specific primer pairs, such that each pair of claim 1 is either SEQ ID NO:1/SEQ ID NO:4; SEQ ID NO:1/SEQ ID NO:5; SEQ ID NO:2/SEQ ID NO:4; SEQ ID NO:2/SEQ ID NO:5; SEQ ID NO:3/SEQ ID NO:4; or SEQ ID NO:3/SEQ ID NO:5. As noted above, the case law is clear that in making a determination of obviousness, the claimed invention as a whole, with all its limitations must be considered and any combination of references must teach or suggest all of the limitations of the invention in order to render the invention obvious. A review of the teachings of Adams et al, in combination with Montagnier et al. and/or Brennan clearly indicates that these requirements have not been met and that this obviousness rejection cannot stand. Adams et al. teaches Primer 3 as part of a primer pair with Primer 1. The nucleotide sequence of Primer 1 bears no similarity to SEQ ID NO:4 or SEQ ID NO:5 of claim 1. Thus, neither Adams et al., alone or in combination with Montagnier et al. and Brennan teach or suggest a pair of oligonucleotide primers wherein the first oligonucleotide of said pair is 10-26 nucleotides in length and comprises at least 10 sequential nucleotides of SEQ ID NOS: 1, 2, or and the second oligonucleotide of the primer pair is 10-26 nucleotides in length and comprises at least 10 sequential nucleotides of SEQ ID NO:4 or 5. As noted above, the case law sets forth the requirement that to support combining or modifying references, there must be particular evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. Clearly, there is no evidence that this combination of references would have led the skilled artisan, absent knowledge of the claimed invention, to select this combination of claimed oligonucleotide pairs.

As yet another reference in this rejection, the Examiner once again cites the

advertisement for software by Research Genetics. As applicants have argued repeatedly and reiterate here again, the Research Genetics Advertisement does nothing to support a prima facie case of obviousness, with any combination of references, and certainly not with this combination. This advertisement provides no specific nucleotide sequence information whatsoever and no amount of "optimization" would produce the oligonucleotide pairs of claim 1, even with the teachings of Montagnier et al, Brennan and/or Adams et al., for all the reasons provided herein, absent knowledge of applicant's specifically claimed oligonucleotide pairs, which employs the use of impermissible hindsight reconstruction to arrive at the present rejection. Thus, for all of these reasons, the oligonucleotide pairs of claim 1 were not obvious to one of ordinary skill in the art at the time this invention was made.

Claims 1-5, 7-9 and 11-12 all depend, either directly or indirectly from claim 1 and recite further limitations that are not taught or suggested in the combination of references cited in this rejection. Thus for the same reasons set forth regarding claim 1, these claims could not have been obvious either.

Applicants note that claim 6 is included in this rejection as stated on page 7, paragraph 16 of the Office Action, although claim 6 is not mentioned in the listing of claims of this rejection on page 11, paragraph 30 of the Office Action. Thus, applicants are unclear whether claim 6 is included in this rejection, but to the extent that it is included, applicants comment as follows.

Claim 6 recites the method according to claim 5 (which depends from claim 1), wherein the detection of amplified HIV-1 nucleic acid is carried out by reacting the sample with one or more oligonucleotide probes having a sequence selected from the group consisting of:
SEQ ID 6: TCT GGT AAC TAG AGA TCC CTC
SEQ ID 7: TAG TGT GTG CCC GTC TGT or
SEQ ID 8: AGT GTG TGC CCG TCT GTT,

one or more of which are provided with a detectable label, under suitable hybridization conditions, and detecting the presence of the label in any hybrids formed between the amplified HIV-1 nucleic acid and the one or more probes.

Not only is claim 6 not obvious as dependent from claim 1 for all the reasons that claim 1 is not obvious, as set forth above, but claim 6 is also not obvious because this claim recites specific oligonucleotides for use as probes to detect the amplification product of the method employing the oligonucleotide primer pairs of claim 1 and none of the references cited in this rejection even remotely suggest any of the oligonucleotides of claim 6 for detection of any amplification product, much less for the detection of an amplification product produced by a method employing a primer pair of claim 1. Thus, it is clear that claim 6 was not obvious to one of ordinary skill in the art in view of the references cited in this rejection, whether considered alone or in any combination.

Applicants also note that claim 13 and its dependent claims 14-18 are included in the present rejection. Claim 13 recites a pair of oligonucleotide primers consisting of:

(i) a first hybridizing oligonucleotide selected from the group consisting of:
SEQ ID 1: G GGC GCC ACT GCT AGA GA;
SEQ ID 2: G TTC GGG CGC CAC TGC TAG A;
SEQ ID 3: CGG GCG CCA CTG CTA; and
SEQ ID 9: aat tct aat acg act cac tat agg gAG AGG GGC GCC ACT GCT AGA GA; and

(ii) a second hybridizing oligonucleotide selected from the group consisting of:
SEQ ID 4: CTG CTT AAA GCC TCA ATA AA; and
SEQ ID 5: CTC AAT AAA GCT TGC CTT GA.

Applicants believe this claim is very clear in its recitation of the term consisting of and that the interpretation of that term as a closed ended term is consistent with its use therein. Thus, to render this claim anticipated or obvious, the

prior art would have to disclose these exact oligonucleotide sequences in the exact combinations recited. Clearly this is not the case in the art cited in this rejection and applicants are unclear as to why claims 13-18 are included in this rejection. Applicants have requested in the April 10, 2003 and September 17, 2003 responses a detailed explanation of why claim 13 in particular is rejected as obvious, but no such explanation has been provided. Should this rejection be maintained, applicants, for a third time, request a detailed written explanation not only from Examiner Sisson, but also separately from his supervisor, Examiner Gary Benzion regarding why these claims in particular are rejected as obvious.

Although applicants believe that all aspects of this rejection have been addressed and that this rejection has been overcome for the reasons set forth above, applicants also point out once again that the Examiner has consistently cited the advertisement by Research Genetics in combination with either McDonough et al. (July 20, 2000 Office Action), Montagnier et al. (February 14, 2001 Office Action and July 31, 2001 Office Action), Montagnier et al. and Backus et al. (April 5, 2002 Office Action, December 18, 2002 Office Action and November 19, 2003 Office Action) and now in combination with Montagnier et al, Adams et al. and Brennan in support of his rejection of all the claims under 35 U.S.C. § 103. Thus, this advertisement has been included in an obviousness rejection of the pending claims seven times now in combination with various other art references, indicating to applicants that although the other art references have varied, it is the Examiner's position that this advertisement in particular is essential in supporting a rejection of the pending claims as obvious. Applicants have reviewed this advertisement and presented detailed arguments to the Examiner in both the December 19, 2000 response and the June 13, 2001 response, setting forth several well-reasoned statements regarding why the use of the software program described in the advertisement by Research Genetics would not produce the oligonucleotides and/or primer pairs of the claimed invention without knowledge of the present invention and with or without the teachings of McDonough et al, Backus et al. and/or Montagnier et

al., thus leading to the reasonable conclusion that this reference does not render the claimed invention obvious. In the April 10, 2003, the September 17, 2003 and February 19, 2004 responses, Applicants have requested a detailed response to these arguments from the Examiner and have even requested that the Examiner "...make of record appropriate evidence indicating all the capabilities of the prior art that is being cited." (page 3, third paragraph of June 13, 2001 response).

However, although the subsequent Office Actions all state that applicants' arguments have been considered and have not been found persuasive in overcoming this rejection, applicants have never received a detailed explanation regarding why applicants' arguments fail to demonstrate that the Research Genetics advertisement does not render the claimed invention obvious. Instead, the same brief paragraph of what is disclosed in the advertisement appears again and again in each subsequent Office Action and there has been no further comment from the Examiner regarding this particular reference or any specific reply to applicants' comments about this reference, with the exception in the November 19, 2003 Office Action (along with some unproductive and prejudicial comments from the Examiner) and the present Office Action of the addition of the statement that the designing of a sequence over that of another is routine optimization. This is clearly not responsive to applicants' request for a detailed explanation specifically addressing applicants' arguments presented in both the December 19, 2000 response and the June 13, 2001 response and applicants' previous request that the Examiner make of record appropriate evidence indicating all the capabilities of the prior art that is being cited so that applicants can properly address this reference.

Thus, should the Examiner maintain this rejection, applicants, for a fourth time, specifically request a detailed written explanation from Examiner Sisson as well as a separate detailed written explanation from the Examiner's supervisor, Mr. Gary Benzion, regarding why these arguments fail to overcome the present rejection, with detailed comment requested that specifically addresses applicants' arguments

regarding the Research Genetics advertisement. Applicants have discussed this issue with Examiner Benzion previously and made a written request for his specific input on this matter in the February 19, 2004 response. Applicants note with appreciation that Examiner Benzion did sign the present Office Action as was also requested by applicants; however, applicants respectfully request both Examiner Sisson's and Examiner Benzion's specific and separate explanations of the matters requested herein should a subsequent Office Action be issued for this application. Applicants make this request again for the purpose of having the opportunity to fully respond to this rejection and to provide a more complete record in the event of an appeal.

B. The Office Action states that claim 6 is rejected under 35 U.S.C. § 103 as allegedly unpatentable over Montagnier et al., Brennan, Adams et al. (the Office Action states Backus et al. but later refers to Adams et al., so Adams et al. will be assumed, as Backus et al. has been removed as a reference), Research Genetics, Boris-Lawrie and McDonough et al. Specifically, the Office Action states that while Montagnier et al. teaches using probes that hybridize to amplicons from HIV LTR, none of the references cited above teach explicitly of an oligonucleotide comprising SEQ ID NOs:6-8.

The Office Action goes on to state that Boris-Lawrie discloses a SEQ ID NO:5 that comprises applicants' SEQ ID NOs:7 and 8 and that McDonough et al. discloses SEQ ID NO:49, which comprises applicants' SEQ ID NO:6.

As noted above, in making an obviousness determination, the invention as a whole, with all its limitations must be considered, and all of the limitations of the claims must be found in the combination of references, absent any knowledge of applicants' invention. Claim 6 recites the method according to claim 5 (which depends from claim 1), wherein the detection of amplified HIV-1 nucleic acid is carried out by reacting the sample with one or more oligonucleotide probes having a sequence selected from the group consisting of:

SEQ ID 6: TCT GGT AAC TAG AGA TCC CTC

SEQ ID 7: TAG TGT GTG CCC GTC TGT or

SEQ ID 8: AGT GTG TGC CCG TCT GTT,

one or more of which are provided with a detectable label, under suitable hybridization conditions, and detecting the presence of the label in any hybrids formed between the amplified HIV-1 nucleic acid and the one or more probes.

Not only is claim 6 not obvious as dependent from claim 1 for all the reasons that claim 1 is not obvious, as set forth above, but claim 6 is also not obvious because this claim recites specific oligonucleotides for use as probes to detect the amplification product of a method employing the specific oligonucleotide primer pair of claim 1 and none of the references cited in this rejection even remotely suggest any of the oligonucleotides of claim 6 for detection of any amplification product, much less for the detection of an amplification product produced by a method employing a primer pair of claim 1, which limitation must be considered in an evaluation of whether the method of claim 6 would have been obvious. In fact, the sequences disclosed in both Boris-Lawrie and McDonough are used as primers in amplification methods and not as probes, thus providing no motivation to one of ordinary skill in the art to select those sequence from the disclosures of Boris-Lawrie and/or McDonough for use in a method of detecting an amplification product resulting from a method employing the specific primer pairs of claim 1. Thus, it is clear that claim 6 was not obvious to one of ordinary skill in the art in view of the references cited in this rejection, whether considered alone or in any combination.

C. The Office Action states that claim 15 is rejected under 35 U.S.C. § 103 as allegedly unpatentable over Montagnier et al. in view of Brennan, Adams et al. and Research Genetics, and further in view of Zaaijer et al. Specifically, the Office Action states that Adams et al. discloses a primer for amplifying HIV that comprises nucleotides corresponding to applicants' SEQ ID NO:1 but that none of the previously described references disclose using primers that comprise a T7 RNA polymerase region. The

Office Action goes on to state that Zaaijer et al. discloses a method of detecting HIV by isothermal amplification or NASBA and that the method comprises using a primer that comprises a T7 RNA polymerase recognition site.

Claim 15 recites the pair of oligonucleotide primers of claim 13, wherein said first hybridizing oligonucleotide is SEQ ID 9: aat tct aat acg act cac tat agg gAG AGG GGC GCC ACT GCT AGA GA and wherein said second hybridizing oligonucleotide is SEQ ID 5: CTC AAT AAA GCT TGC CTT GA. As noted above, claim 13 recites a pair of oligonucleotide primers consisting of:

(i) a first hybridizing oligonucleotide selected from the group consisting of:
SEQ ID 1: G GGC GCC ACT GCT AGA GA;
SEQ ID 2: G TTC GGG CGC CAC TGC TAG A;
SEQ ID 3: CGG GCG CCA CTG CTA; and
SEQ ID 9: aat tct aat acg act cac tat agg gAG AGG GGC GCC ACT GCT AGA GA; and

(ii) a second hybridizing oligonucleotide selected from the group consisting of:
SEQ ID 4: CTG CTT AAA GCC TCA ATA AA; and
SEQ ID 5: CTC AAT AAA GCT TGC CTT GA.

Claim 15 is thus a limitation on claim 13, which requires that the primer pair specifically be SEQ ID NO:9 and SEQ ID NO:5. As also noted above with regard to claim 13, in order to render this claim anticipated or obvious, the prior art would have to disclose or suggest these exact oligonucleotide sequences in this exact combination. Clearly this is not the case in the art cited in this rejection. Should this rejection be maintained, applicants again request a detailed written explanation not only from Examiner Sisson, but also separately from Examiner Benzion regarding why these claims in particular are rejected as obvious. Applicants also again request that Examiner Benzion review and sign any subsequent Office Actions issued for this application.

For all the reasons set forth above, applicants believe that the pending rejections in this application have been overcome and their withdrawal is respectfully requested. Applicants again emphasize that the Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. Applicants also reiterate their previous request that all subsequent communications and actions regarding this application be reviewed and co-signed by Supervisory Examiner Benzion. **In particular, should the Examiner make a determination that none of the claims presented herein are allowable, applicants respectfully request a telephone interview with the Examiner, the Examiner's supervisor and a Technical Specialist PRIOR to the issuance of a final Office Action.**

A check in the amount of $110.00 as fee for a one month extension of time is enclosed. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account 50-0220.

Respectfully submitted,

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Cathy A. Schetzina